

PTO/SB/21 (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

| | |
|------------------------|-----------------------|
| Application Number | 10/057,534 |
| Filing Date | 01/25/2002 |
| First Named Inventor | Harry R. Davis et al. |
| Art Unit | 1617 |
| Examiner Name | Shengjun Wang |
| Attorney Docket Number | CV01378K |

Total Number of Pages in This Submission

9

ENCLOSURES (Check all that apply)

| | | |
|--|---|--|
| <input checked="" type="checkbox"/> Fee Transmittal Form | <input type="checkbox"/> Drawing(s) | <input type="checkbox"/> After Allowance communication to Group |
| <input type="checkbox"/> Fee Attached | <input type="checkbox"/> Licensing-related Papers | <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences |
| <input type="checkbox"/> Amendment/Reply | <input type="checkbox"/> Petition | <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) |
| <input type="checkbox"/> After Final | <input type="checkbox"/> Petition to Convert to a Provisional Application | <input type="checkbox"/> Proprietary Information |
| <input type="checkbox"/> Affidavits/declaration(s) | <input type="checkbox"/> Power of Attorney, Revocation | <input type="checkbox"/> Status Letter |
| <input type="checkbox"/> Extension of Time Request | <input type="checkbox"/> Change of Correspondence Address | <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): |
| <input type="checkbox"/> Express Abandonment Request | <input type="checkbox"/> Terminal Disclaimer | PTO-1449 - 1 Page in duplicate; |
| <input checked="" type="checkbox"/> Information Disclosure Statement | <input type="checkbox"/> Request for Refund | (1) Reference; Post Card |
| <input type="checkbox"/> Certified Copy of Priority Document(s) | <input type="checkbox"/> CD, Number of CD(s) _____ | |
| <input type="checkbox"/> Response to Missing Parts/Incomplete Application | Remarks | |
| <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | | |

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | |
|-------------------------|------------------------------------|
| Firm or Individual name | Ann Marie Cannoni, Reg. No. 35,972 |
| Signature | |
| Date | 01/15/2004 |

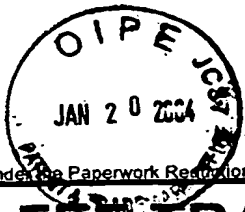
CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

| | | | |
|-----------------------|------------------------------------|------|------------|
| Typed or printed name | Ann Marie Cannoni, Reg. No. 35,972 | | |
| Signature | | Date | 01/15/2004 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Image

1017/18

Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 180.00

Complete if Known

| | |
|----------------------|-----------------------|
| Application Number | 10/057,534 |
| Filing Date | 01/25/2002 |
| First Named Inventor | Harry R. Davis et al. |
| Examiner Name | Shengjun Wang |
| Art Unit | 1617 |
| Attorney Docket No. | CV01378K |

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit
Account
Number
Deposit
Account
Name

19-0365

Schering-Plough Corporation

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

| Large Entity | | Small Entity | | Fee Description | Fee Paid |
|--------------|----------|--------------|----------|------------------------|----------|
| Fee Code | Fee (\$) | Fee Code | Fee (\$) | | |
| 1001 | 770 | 2001 | 385 | Utility filing fee | |
| 1002 | 340 | 2002 | 170 | Design filing fee | |
| 1003 | 530 | 2003 | 265 | Plant filing fee | |
| 1004 | 770 | 2004 | 385 | Reissue filing fee | |
| 1005 | 160 | 2005 | 80 | Provisional filing fee | |
| SUBTOTAL (1) | | | | | (\$ 0.00 |

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

| | | Extra Claims | | Fee from below | | Fee Paid |
|--------------------|--|--------------|--|----------------|--|----------|
| Total Claims | | | | | | |
| Independent Claims | | -20** = | | X | | |
| Multiple Dependent | | -3** = | | X | | |

| Large Entity | | Small Entity | | Fee Description | Fee Paid |
|--------------|----------|--------------|----------|--|----------|
| Fee Code | Fee (\$) | Fee Code | Fee (\$) | | |
| 1202 | 18 | 2202 | 9 | Claims in excess of 20 | |
| 1201 | 86 | 2201 | 43 | Independent claims in excess of 3 | |
| 1203 | 290 | 2203 | 145 | Multiple dependent claim, if not paid | |
| 1204 | 86 | 2204 | 43 | ** Reissue independent claims over original patent | |
| 1205 | 18 | 2205 | 9 | ** Reissue claims in excess of 20 and over original patent | |

SUBTOTAL (2) (\$ 0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

| Large Entity | | Small Entity | | Fee Description | Fee Paid |
|--------------|----------|--------------|----------|--|----------|
| Fee Code | Fee (\$) | Fee Code | Fee (\$) | | |
| 1051 | 130 | 2051 | 65 | Surcharge - late filing fee or oath | |
| 1052 | 50 | 2052 | 25 | Surcharge - late provisional filing fee or cover sheet | |
| 1053 | 130 | 1053 | 130 | Non-English specification | |
| 1812 | 2,520 | 1812 | 2,520 | For filing a request for <i>ex parte</i> reexamination | |
| 1804 | 920* | 1804 | 920* | Requesting publication of SIR prior to Examiner action | |
| 1805 | 1,840* | 1805 | 1,840* | Requesting publication of SIR after Examiner action | |
| 1251 | 110 | 2251 | 55 | Extension for reply within first month | |
| 1252 | 420 | 2252 | 210 | Extension for reply within second month | |
| 1253 | 950 | 2253 | 475 | Extension for reply within third month | |
| 1254 | 1,480 | 2254 | 740 | Extension for reply within fourth month | |
| 1255 | 2,010 | 2255 | 1,005 | Extension for reply within fifth month | |
| 1401 | 330 | 2401 | 165 | Notice of Appeal | |
| 1402 | 330 | 2402 | 165 | Filing a brief in support of an appeal | |
| 1403 | 290 | 2403 | 145 | Request for oral hearing | |
| 1451 | 1,510 | 1451 | 1,510 | Petition to institute a public use proceeding | |
| 1452 | 110 | 2452 | 55 | Petition to revive - unavoidable | |
| 1453 | 1,330 | 2453 | 665 | Petition to revive - unintentional | |
| 1501 | 1,330 | 2501 | 665 | Utility issue fee (or reissue) | |
| 1502 | 480 | 2502 | 240 | Design issue fee | |
| 1503 | 640 | 2503 | 320 | Plant issue fee | |
| 1460 | 130 | 1460 | 130 | Petitions to the Commissioner | |
| 1807 | 50 | 1807 | 50 | Processing fee under 37 CFR 1.17(q) | |
| 1806 | 180 | 1806 | 180 | Submission of Information Disclosure Stmt | 180.00 |
| 8021 | 40 | 8021 | 40 | Recording each patent assignment per property (times number of properties) | |
| 1809 | 770 | 2809 | 385 | Filing a submission after final rejection (37 CFR 1.129(a)) | |
| 1810 | 770 | 2810 | 385 | For each additional invention to be examined (37 CFR 1.129(b)) | |
| 1801 | 770 | 2801 | 385 | Request for Continued Examination (RCE) | |
| 1802 | 900 | 1802 | 900 | Request for expedited examination of a design application | |

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ 180.00

SUBMITTED BY

| | | | | | |
|-------------------|-------------------|-----------------------------------|------------|-----------|--------------|
| Name (Print/Type) | Ann Marie Cannoni | Registration No. (Attorney/Agent) | 35,972 | Telephone | 908-298-5024 |
| Signature | | Date | 01/15/2004 | | |

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS
SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

JAN 20 2004

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Harry R. Davis, et al.

Examiner: Shengjun Wang

Serial No.: 10/057,534

Group Art Unit: 1617

Filed: January 25, 2002

Atty. Docket No.: CV01378K

For: Combinations of Bile Acid
Sequestrant(s) and Sterol
Absorption Inhibitor(s) and
Treatments for Vascular Indications

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to Rule 56, it is requested that the documents listed on the accompanying PTO-1449 Form be considered and made of record in the above-identified patent application. Copy(ies) of these references ☒ are attached ☐ were filed in related application U.S. Serial No(s) _____ filed _____, respectively.

(b) No fee is believed due because:

- ☐ This Information Disclosure Statement is being filed within three (3) months of the filing date of the application.
- ☐ This Information Disclosure Statement is being concurrently filed with the above-identified application.
- ☐ This Information Disclosure Statement is being concurrently filed with a Request for Continued Examination (RCE).
- ☐ This Information Disclosure Statement is being filed prior to the mailing of a first Office Action on the merits.

(c) ☒ This Information Disclosure Statement is being filed before the mailing date of any final action, notice of allowance or an action that otherwise closes prosecution; and

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; or

01/22/2004 DTESSEM1 00000146 190365 10057534

01 FC:1806


180.00 DA

- ☒ The Commissioner is hereby authorized to charge the requisite fee listed on the attached Fee Transmittal Sheet.
- (d) ☐ This Information Disclosure Statement is being filed on or before the payment of the issue fee; and
- ☐ Each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and
- ☐ The Commissioner is hereby authorized to charge the requisite fee listed on the attached Fee Transmittal Sheet.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 19-0365, Patent Case No. CV01378K. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,
SCHERING-PLOUGH CORPORATION

Dated: January 15, 2004
SCHERING-PLOUGH CORPORATION
Patent Department, K-6-1, 1990
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530
Facsimile No.: (908) 298-5388

By:

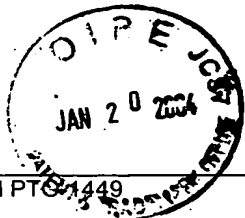

Name: **Ann M. Cannoni**
Reg. No.: **35,972**
Attorney of Record
Telephone No.: (908) 298-5024

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450 ON October 30, 2003 AMC
(DATE OF DEPOSIT)

January 15, 2004

ANN MARIE CANNONI, REG. NO. 35,972
(REGISTERED REPRESENTATIVE)


(SIGNATURE AND DATE)



| | | | |
|---|--|--|----------------------------------|
| FORM PTO-1449 | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | ATTY. DOCKET NO.: CV01378K | SERIAL NO.: 10/057,534 |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) | | APPLICANT: Harry R. Davis et al. | |
| | | FILING DATE: 01/25/2002 | GROUP: 1615 |

U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB- CLASS | FILING DATE IF APPROPRIATE |
|----------------------|----|--------------------|------|------|-------|---------------|-------------------------------|
| | AA | | | | | | |
| | AB | | | | | | |
| | AC | | | | | | |
| | AD | | | | | | |
| | AE | | | | | | |
| | AF | | | | | | |
| | AG | | | | | | |
| | AH | | | | | | |
| | AI | | | | | | |
| | AJ | | | | | | |
| | AK | | | | | | |

FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB- CLASS | TRANSLATION | |
|--|----|--------------------|------|---------|-------|---------------|-------------|----|
| | | | | | | | YES | NO |
| | AL | | | | | | | |
| | AM | | | | | | | |
| | AN | | | | | | | |
| | AO | | | | | | | |
| | AP | | | | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | | |
|--|----|---|
| | AQ | ZETIA™ (ezetimibe) Tablets Package Insert (Merck/Schering-Plough Pharmaceuticals) (October 2002) |
| | AR | |
| | AS | |
| | AT | |
| | AU | |
| | AV | |

| | |
|----------|-----------------|
| EXAMINER | DATE CONSIDERED |
|----------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.